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**AUTHORITY**

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PRIMARY IRRITATION EVALUATION PROGRAM STUDY  
STUDY NUMBERS 33-004-70, 33-006-70 AND 33-015-70  
JANUARY - MARCH 1970



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DEPARTMENT OF THE ARMY  
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY  
EDGEWOOD ARSENAL, MARYLAND 21010

86 MAY 1970

USAEHA-MT

PRIMARY IRRITATION EVALUATION PROGRAM STUDY  
STUDY NUMBERS 33-004-70, 33-006-70 AND 33-015-70  
JANUARY - MARCH 1970

ABSTRACT

Three candidate repellents were evaluated on New Zealand White rabbits for their potential to cause skin and eye irritation. This was used as a basis for making the following recommendations concerning their use on humans.

- a. There is no restriction for acute application of ENT-28675-aGa to the human skin. Irritation of human eyes is not expected if the compound should accidentally get into the eyes, provided it is washed out as soon as possible.
- b. ENT-28670-aGa should be used only on human skin found by examination to have no abrasions or may be used in clothing. Ethanol does not significantly affect the minimal irritation of the skin caused by this compound.
- c. ENT-32932-aGb should not be used in studies involving human skin contact.



USAEHA-MT

DEPARTMENT OF THE ARMY  
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY  
EDGEWOOD ARSENAL, MARYLAND 21010

25 MAY 1970

PRIMARY IRRITATION EVALUATION PROGRAM STUDY  
STUDY NUMBERS 33-004-70, 33-006-70 AND 33-015-70  
JANUARY - MARCH 1970

1. REFERENCES.

a. Memorandum of Understanding between the Department of the Army, Office of The Surgeon General; Armed Forces Pest Control Board and the United States Department of Agriculture effective July 1967.

b. Letter, US Department of Agriculture, Gainesville, Florida, dated 8 August 1969, to this Agency.

c. Toxicology Division Procedural Guide, USAEHA, 1968 (Revised 1969)

2. PURPOSE. This report classifies the candidate repellents listed according to the categories described in the Appendix as determined by a study of their effects on the skin and eyes of rabbits. The information contained in this report is intended only for guidance in further entomological testing of the compounds.

3. SUMMARY OF FINDINGS. The categories assigned to the test compounds are based upon their ability to cause primary irritation of the skin and eyes of New Zealand White rabbits. Compounds which are solids were tested as the technical grade material and also diluted in ethanol. Ethanol dilutions were not tested in the eye. The following compounds are classified according to the categories listed and defined in the Appendix:

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Study Numbers	ENT Nos.	PIEP Categories		Compound Chemical Names
		Skin	Eyes	
33-004-70	28670-aGa	II	-	N-(o-Nitrophenyl)maleimide
		II	-	N-(o-Nitrophenyl)maleimide in ethyl alcohol
33-006-70	28675-aGa	I	A	4-Nitro-N-propylphthalimide
		I	-	4-Nitro-N-propylphthalimide in ethyl alcohol
33-015-70	32932-aGb	VI	-	N-m-Tolylmaleimide

4. RECOMMENDATIONS. Recommendations pertaining to individual compounds in this study can be found in the Appendix by referring to each compound's PIEP category. Those compounds found to be irritating to either the skin or the eyes should be resubmitted in the form and at the concentration of their intended use so that their irritation potential can be reexamined.



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APPENDIX  
DEFINITIONS OF CATEGORIES OF COMPOUNDS  
PRIMARY IRRITATION EVALUATION PROGRAM

Category I - Compounds producing no primary irritation of the intact skin or of the skin surrounding an abrasion.

(Interpretation - There is no restriction for acute application to the human skin.)

Except when specifically requested for individual compounds, the following Eye Injury Categories, A through F, are determined only for those compounds which are in Category I.

- A. Compounds noninjurious to the eye.  
(Interpretation - Irritation of human eyes is not expected if the compound should accidentally get into the eyes, provided it is washed out as soon as possible.)
- B. Compounds producing mild injury to the cornea.  
(Interpretation - Compounds should be used with caution around the eyes.)
- C. Compounds producing mild injury to the cornea and, in addition, some injury to the conjunctiva.  
(Interpretation - Compounds should be used with caution around the eyes and mucosa.)
- D. Compounds producing moderate injury to the cornea.  
(Interpretation - Compounds should be used with extreme caution around the eyes.)
- E. Compounds producing moderate injury to the cornea and, in addition, producing some injury to the conjunctiva.  
(Interpretation - Compounds should be used with extreme caution around the eyes and mucosa.)
- F. Compounds producing severe injury to the cornea and to the conjunctiva.  
(Interpretation - Compounds should be used with extreme caution. It is recommended that use be restricted to areas other than the face.)

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APPENDIX (Cont)

Category II - Compounds producing no primary irritation of the intact skin but producing mild primary irritation of the skin surrounding an abrasion.

(Interpretation - Compounds should be used only on human skin found by examination to have no abrasions or may be used in clothing.)

Category III - Compounds producing mild primary irritation of the intact skin and of the skin surrounding an abrasion.

(Interpretation - Compounds should be used with extreme caution on the skin or may be used in clothing.)

Category IV - Compounds producing moderate primary irritation of the intact skin and of the skin surrounding an abrasion.

(Interpretation - Compounds should not be used directly on the skin but may be used as clothing impregnants with extreme caution.)

Category V - Compounds producing moderate primary irritation of the intact skin and of the skin surrounding an abrasion and, in addition, producing necrosis, vesiculation, ulceration and/or eschars.

(Interpretation - Compounds should not be used in studies involving human skin contact.)

Category VI - Compounds producing severe primary irritation of the intact skin and of the skin surrounding an abrasion and, in addition, producing necrosis, vesiculation, ulceration and/or eschars.

(Interpretation - Compounds should not be used in studies involving human skin contact.)

Category VII - Compounds impossible to classify because of staining of the skin or because of other masking effects due to physical properties.

(Interpretation - Compounds are not suitable for use on humans.)

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b. ENT-28670-aGa should be used only on human skin found by examination to have no abrasions or may be used in clothing. Ethanol does not significantly affect the minimal irritation of the skin caused by this compound.		
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14. KEY WORDS	LINK A		LINK B		LINK C	
	ROLE	WT	ROLE	WT	ROLE	WT
ENT-28670-Ga ENT-28675-Ga ENT-32932-Gb <b>Ethanol</b> <b>Toxicity</b> N-(o-Nitrophenyl)maleimide 4-Nitro-N-propylphthalimide N-m-Tolylmaleimide						

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